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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

APR 23 1999

Re: ALDARA™
Docket No. 97E-0269
Docket No. 97E-0270

#18

The Honorable Q. Todd Dickinson
Deputy Assistant Commissioner for
Patent Policy and Projects
Office of the Assistant Commissioner for Patents
U.S. Patent and Trademark Office
Crystal Park Building 2, Suite 919
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the patent term extension applications for U.S. Patent Numbers. 5,238,944 and 4,689,338 filed by Riker Laboratories under 35 U.S.C. § 156. The patents claim the human drug product ALDARA™ (imiquimod), new drug application NDA 20-723.

In the October 20, 1998 and October 15, 1998 , issues of the Federal Register (63 Fed. Reg. 56035 and 55398), the Food and Drug Administration published its determination of this product's regulatory review period, as required under 35 U.S.C. § 156(d)(2)(A). The notices provided that on or before April 19, 1999, and April 13, 1999, 180 days after the publications of the determinations, any interested person could file a petition with FDA under 35 U.S.C. § 156(d)(2)(B)(i) for a determination of whether the patent term extension applicant acted with due diligence during the regulatory review period.

The 180-day periods for filing a due diligence petition pursuant to these notices have expired and FDA has received no such petitions. Therefore, FDA considers the regulatory review period determinations to be final.

Please let me know if we can provide further assistance.

Sincerely yours,

Ronald L. Wilson

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs

cc: Ted K. Ringsred
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